510(K) SUMMARY

SUBMITTER INFORMATION

A.	Company Name:	IntraLuminal Therapeutics, Inc.
B.	Company Address:	6354 Corte Del Abeto – Suite A Carlsbad, CA 92009
C.	Company Phone:	(760) 918-1820
D.	Company Facsimile:	(760) 603-9615
E.	Contact Person:	Pamela Misajon Vice President of Regulatory Affairs and Quality Assurance

DEVICE IDENTIFICATION

A.	Device Trade Name:	Safe-Cross Radio Frequency Total Occlusion Crossing System
B.	Device Common Name:	Guidewire
D.	Classification Name:	Catheter Guidewire
E.	Device Class:	Class II (per 21 CFR 870.1330)

IDENTIFICATION OF PREDICATE DEVICE

The principal predicate device is the Safe-Steer™ Guide Wire System, manufactured by Intraluminal Therapeutics and cleared under 510(k) Premarket Notification number K021323. Another predicate device is the Hydrophilic Coated Guidewire by Lake Region Manufacturing, which was cleared under 510(k) Premarket Notification number K003483.

DEVICE DESCRIPTION

The Safe-Cross™ Radio Frequency (RF) Total Occlusion (TO) Crossing System consists of a the following:

- 0.014" Safe-Cross RF Crossing Wire – Straight and Angled Tip (with Torquer)
- 0.035" Safe-Cross RF Crossing Wire – Straight and Angled Tip (with Torquer)
- Safe-Steer™ Optical Coherence Reflectometry (OCR) Unit with Display Monitor

- Safe-Cross RF Generator with Footswitch and Interface Cable

The Safe-Cross RF Crossing Wires are similar to the predicate guidewires in construction and intended use. The proximal end of the Crossing Wire is connected to a Y-Site hub that houses the optic fiber connector and the RF connector. The optical connector is connected to the OCR Unit to allow the medical practitioner to visualize structures within the vessel for navigation purposes. The RF connector is connected to the RF Generator. This allows the medical practitioner to provide discrete RF energy to the distal tip to assist in moving the wire tip through the occlusion in the vessel.

The RF Crossing Wire is packaged in a Tyvek® sealed plastic tray. The packaged RF Crossing Wire is sterilized by ethylene oxide gas. The packaged RF Crossing Wire is provided "STERILE" and Non-pyrogenic, and is intended for single use only.

INTENDED USE

The Safe-Cross® Radio Frequency Total Occlusion Crossing System is indicated for use in facilitating the placement of devices used in vascular interventions of total occlusions in native iliac and superficial femoral arteries (SFA) of the lower extremities.

TECHNOLOGICAL CHARACTERISTICS

The components of the Safe-Cross System are similar in basic materials, design, construction and performance to the predicate devices. The RF Generator is an additional component of the Safe-Cross System. The performance of the RF Generator has been verified through bench, animal, and human clinical studies.

BIOCOMPATIBILITY AND PERFORMANCE DATA

Biocompatibility testing, *in vitro* bench testing and *in vivo* animal studies were conducted to evaluate the biological and performance characteristics of the Safe-Cross System. Biocompatibility test results indicate that the patient contact components of the Safe-Cross Crossing Wire are biocompatible. Benchtop performance test results indicate that the components of the Safe-Cross System satisfy safety and performance requirements of the device specifications. *In Vivo* animal studies demonstrate that the various components of the Safe Cross System function together, as intended, in the animal model and do not raise unanticipated safety issues.

CLINICAL STUDIES

Human clinical studies have been conduct to verify the safety and performance characteristics of the Safe-Cross System when used in human subjects for the indicated use of crossing total occlusions in native iliac and superficial arteries (SFA) of the lower

extremities. The results of the clinical studies indicate that the device performs as intended and does not involve unacceptable risk to the patient.

CONCLUSIONS DRAWN FROM STUDIES

The results of nonclinical and clinical testing demonstrate that Safe-Cross System is substantially equivalent to the predicate devices and satisfies the requirements of the device specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Intraluminal Therapeutics, Inc.
c/o Ms. Pamela Misajon
6354 Corte del Abeto, Suite A
Carlsbad, CA 92009

SEP 18 2013

Re: K031842
Trade/Device Name: Safe-Cross Radio Frequency Total Occlusion Crossing System [Peripheral]
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: September 19, 2003
Received: September 22, 2003

Dear Ms. Misajon:

This letter corrects our substantially equivalent letter of November 21, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K031842

Device Name: Safe-Cross® RF TO Crossing System

Indications For Use: The Safe-Cross® Radio Frequency Total Occlusion Crossing System is indicated for use in facilitating the placement of devices used in vascular interventions of total occlusions in native iliac and superficial femoral arteries (SFA) of the lower extremities.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031842